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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/833,637	04/13/2001	Yoshikatsu Kodama	011900-309	3072

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EXAMINER

KAM, CHIH MIN

ART UNIT

PAPER NUMBER

1653

DATE MAILED: 04/04/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/833,637

Applicant(s)

KODAMA ET AL.

Examiner

Chih-Min Kam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 January 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16-27 and 29 is/are rejected.
- 7) ☒ Claim(s) 28 and 30 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Applicants' submission of English translation of Japanese Application 2000-113912 is acknowledged. Applicants is required to provide a certified copy of Japanese Application 2000-113912 since applicant claims for foreign priority under 35 U.S.C. 119(a)-(d).

Status of the Claims

1. Claims 16-30 are pending.

Applicants' amendment filed on January 22, 2002 (Paper No. 5) is acknowledged and applicants' response has been fully considered. Claims 1-11 have been cancelled, claims 12-15 stand withdrawn, and new claims 16-30 have been added and are under examination.

Election/Restrictions

2. Applicant's election with traverse of Group I, claims 1-11 is acknowledged. The traversal is on the ground(s) that the search can be made without burden, and claims 12-15 are linked to Group I as product and process of use. This is not found persuasive because applicant's response has not demonstrated there is no additional burden of search to include Group II (claims 12 and 13) and Group III (claims 14 and 15). Restriction is proper when two or more claimed inventions are either independent or distinct. See MPEP 803. Furthermore, coexamination of each of the additional groups would have required a search of additional art areas. For example, including Group III, it would require additional searches for gastrointestinal diseases. Therefore, coexamination of each of these inventions would require a serious additional burden of search.

The restriction groups have acquired a separate status in the art as a separate subject for inventive effect and require independent searches. The search for each of the invention is not coextensive particularly with regard to the literature search. A reference which would anticipate

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the invention of one group would not necessarily anticipate or make obvious any of the other group. Moreover, as to the question of burden of search, classification of subject matter is merely one indication of the burdensome nature of the search involved. The literature search, particularly relevant in this art, is not co-extensive and is much more important in evaluating the burden of search. Burden in examining materially different groups having materially different issues also exist.

The requirement is still deemed proper and is therefore made FINAL.

Objection Withdrawn

3. The previous objection to claims 1-11 regarding misspelling of “glycoprotein” and use of “albumen” or “*Helicobacter pylori*”, is withdrawn in view of applicants’ cancellation of claims 1-11, making corrections in new claims, and applicants’ response at pages 6-7 in Paper No. 5.

Rejection Withdrawn

Claim Rejections - 35 USC § 101

4. The previous rejection of claim 1, under 35 U.S.C.101, regarding the claimed invention being directed to non-statutory subject matter, is withdrawn in view of applicants’ cancellation of the claim, and applicants’ response at page 7 in Paper No. 5.

Claim Rejections - 35 USC § 112

5. The previous rejection of claims 1, 4-6, 8-9 and 11, under 35 U.S.C.112, second paragraph, regarding “specifically binds”, “derived from”, “and/or” or “a disease”, is withdrawn in view of applicants’ cancellation of the claims, making corrections in new claims, and applicants’ response at pages 8-9 in Paper No. 5.

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Claim Rejections - 35 USC § 102

6. The previous rejection of claims 1-11, under 35 U.S.C.102(e), is withdrawn in view of applicants' cancellation of the claims and applicants' response at pages 8-9 in Paper No. 5.

Claim Rejections-Obviousness Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 16-20 and 22-26 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 of U. S. Patent 6,235,709. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 16-20 and 22-26 in the instant application disclose a glycoprotein which specifically binds to urease of *Helicobacter pylori*, and is isolated from a whey of bovine milk by affinity chromatography immobilized with urease; an inhibitor of *Helicobacter pylori* colonization comprising the glycoprotein; a pharmaceutical composition comprising the glycoprotein; a food comprising the glycoprotein; an inhibitor composition of *Helicobacter pylori* colonization comprising the glycoprotein and an inhibitor of gastric acid secretion; and an pharmaceutical composition associated with *Helicobacter pylori* comprising the glycoprotein and an inhibitor of gastric acid secretion. This is obvious in view of claims 1-7

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in the patent which disclose an inhibitor of *Helicobacter pylori* colonization comprising a mucin, which can bind *Helicobacter pylori* urease specifically, and is isolated from a whey of bovine milk by treatment with membrane; an inhibitor composition of *Helicobacter pylori* colonization comprising the mucin and an inhibitor of gastric acid secretion; an inhibitor composition of *Helicobacter pylori* urease comprising a mucin which can bind urease specifically and an inhibitor of gastric acid secretion; and a food comprising an inhibitor of *Helicobacter pylori* colonization comprising the mucin. Both sets of claims cite a glycoprotein or mucin, which is isolated from whey of bovine milk, and is an inhibitor of *Helicobacter pylori* colonization, which can bind *Helicobacter pylori* urease specifically. Thus, claims 16-20 and 22-26 in present application and claims 1-7 in the patent are obvious variations of a glycoprotein or mucin which is isolated from whey of bovine milk, and is an inhibitor of *Helicobacter pylori* colonization, which can bind *Helicobacter pylori* urease specifically; an inhibitor composition of *Helicobacter pylori* colonization comprising the glycoprotein and an inhibitor of gastric acid secretion; and a food comprising an inhibitor of *Helicobacter pylori* colonization comprising the glycoprotein.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 16, 19-26, 27 and 29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
9. Claims 16, 19-26, 27 and 29 are indefinite because of the use of the term “a method which utilizes specific adsorption to *Helicobacter pylori* urease”. The term “a method which

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utilizes specific adsorption to *Helicobacter pylori* urease” renders the claim indefinite, it is unclear which method is used for purification of the glycoprotein. Claims 19-26 are included in the rejection because they are dependent on rejected claims and do not correct the deficiency of the claim from which they depend.

10. Claim 25 is indefinite because of the use of the term “an inhibitor of gastric acid secretion”. The term “an inhibitor of gastric acid secretion” renders the claim indefinite, it is unclear what compound is as to an inhibitor of gastric acid secretion.

11. Claims 28 and 30 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

12. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (703) 308-9437. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Christopher Low, Ph. D. can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

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Chih-Min Kam, Ph. D. *CMK*
Patent Examiner

March 24, 2002

A handwritten signature in black ink, reading "Karen Cochrane Carlson PhD". The signature is written in a cursive, flowing style.

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER